

REMARKS

Claims

Claims 1–28, which were originally-presented, are under examination.

Claim amendments

The amendment of claims 1, 5, 9, 13, 27 and 28 is supported by the disclosure in, for example, paragraph [0032] of the published US specification (US app. publ. No. 2008-0045853). See also paragraph [0009] of the published US specification, wherein it is expressly stated that “terms “preseizure” and “impending seizure” are used interchangeably to indicate the neural state that precedes the characteristic neural activity described as a “seizure.””

It is respectfully submitted that the amendments do not recite new matter. Entry thereof is respectfully requested.

Drawings

A copy of Fig. 3 from US provisional appl. No. 60/422,870, which is incorporated by reference in its entirety in the present application, is enclosed herewith as a replacement figure for the PTO’s consideration. Inasmuch as a certified copy of the priority document was forwarded to the USPTO with the original application papers on April 29, 2005, the amendment of the DRAWINGS section complies with 37 CFR § 1.57. No new matter is added.

The objection of Figures 4–7 for having “filled triangles, squares, and circles,” the denotation of which is “unclear” is respectfully traversed. It is clear to those skilled in the art that inasmuch as Figures 4–7 depict grey-scale plots of time-dependent changes in individual parameters (e.g., RMS Activity per Phase (σ) or Normalized RMS deviation ($\Delta = (\sigma - \bar{\sigma}_i) / \bar{\sigma}_i$)], the triangles, squares and circles distinguish one plot over the other (i.e., they depict individual measurements). Such techniques were almost universally used in printing prior to the wide-spread use of color printers and/or digital publishing. Thus, the meaning(s) of the symbols or reference characters that appear in the Drawings is clear to those skilled in the art. See MPEP §608.02. Withdrawal of the rejection is respectfully requested.

Rejections under §112, ¶2

The amendment of claims 1, 5, 9, 13, 27 and 28 renders the various rejections under this section moot. Applicants' amendment of the claims should not be construed as acquiescence to this or any other ground of rejection set forth in the Office Action. Withdrawal of the rejection is respectfully requested.

Rejections under §102/§103

Claims 1-17, 21-23 and 25-28 are rejected under §102(b) as allegedly anticipated by Archer et al. (US patent No. 6,690,974). Moreover, the Examiner at page 7 of the Office Action contends that the subject matter of claims 18-24 and 24 is unpatentable over the aforementioned Archer et al. in view of Gluckman et al. (US patent No. 6,665,562). These rejections are respectfully traversed.

In the context of the subject matter of the instant claims, the USPTO appears to allege that Archer's disclosure of non-responsive stimulation is equivalent to the response following stimulation, as recited in the instant claims. This interpretation is incorrect. Archer uses non-responsive stimulation (NRS) to mean open loop and not in the context of measurements which are indicative of brain dynamics. Therefore, the PTO's reliance on the disclosure in col. 15, lines 36–51 of Archer to support its rejection is without merit. To this end, the Examiner is requested to note that the present application utilizes a method wherein neural system is subjugated to “sub-threshold” stimuli and the response thereto is detected. This is substantially different from what is employed by Archer et al. and the two methods are not equivalent to one another. In this regard, for example, paragraph [0016] of the published US specification and the disclosure in the Examples section provides a detailed disclosure on the types of stimuli employed in the instant application.

Archer is directed to the neuro-pace concept of a seizure control device with two main stimulation operating modes: non-responsive, and responsive. The non-responsive case is equivalent to open loop stimulation. The responsive case is another stimulation mode applied when an impending seizure is detected. It is stated that such seizure detection can be done either during non-responsive stimulation

(NRS), or when NRS is turned off. In the descriptive portion of the Archer patent, the various types of non-responsive stimulation (e.g., pulse, sinusoid, arbitrary waveform) are outlined. Archer further provides guidance on ways to conduct simultaneous measurement of brain activity, especially in reference to blanking. Archer does not teach or suggest methods of seizure anticipation, e.g., detecting an impending seizure or a pre-seizure, as recited in the claims.

As expressly stated under MPEP §2131, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” See *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987). For processes, MPEP §2106 states that “the claim limitations will define steps or acts to be performed.” Not only is Archer generally silent with respect to detecting an impending seizure or a pre-seizure but the reference says nothing about all the acts or steps to be employed in such detection, as recited in instant claims. More specifically, the totality of disclosure in Archer says nothing about the use of an electrical stimulus consisting of low frequency content to a neural system and the dual detection of a first response of the neural system to the stimulus during a first control state (e.g., an interictal state) and a second post-stimulus state (e.g., a state indicative of an impending seizure or a state indicative of pre-seizure), the difference between the two states being used to make a determination of the impending seizure. Accordingly, Archer fails to anticipate the subject matter of instant claims 1, 5, 9, 13, 27 and 28.

Withdrawal of the rejection is respectfully requested.

Obviousness rejection

Applicants respectfully submit that one of ordinary skill in the art cannot arrive at the present invention by merely combining the cited references because the asserted combination of Archer et al. and Gluckman et al., even at its broadest interpretation, fails to teach all the elements of the claimed invention. The necessary presence of all claim features in the cited art is axiomatic, since the Supreme Court has long held that obviousness is a question of law based on underlying factual inquiries, including ... ascertaining the differences between the claimed invention

and the prior art (*Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966)). As to the elements in a process claim, MPEP §2106 states that “for process claims, the claim limitations will define steps or acts to be performed.” Neither Archer nor Gluckman teaches the steps involved in determination of impending seizure in a neural system, as recited in the instant claims. To this end, Appellants direct the PTO’s attention to *In re Wada and Murphy*, Appeal 2007-3733, which reversed a §103 rejection because the Examiner did not explain where or how cited art taught or suggested all of the features of a claimed invention. See, for example, the following BPAI articulation of applicable law:

When determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention - including all its limitations - with the teaching of the prior art.” *In re Ochial*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

Applicants aver that the elements of independent claims 1, 5, 9, 13, 27 and 28 are not taught or suggested by the asserted combination of references. This is fatal to an obviousness rejection under 35 U.S.C. §103(a). To this end, §2143.03 of the MPEP requires “consideration” of every claim feature in an obviousness determination. To render the claims unpatentable, however, the Patent Office must do more than merely “consider” each and every feature for this claim. Instead, the asserted combination of Archer and Gluckman must also *teach or suggest each and every claim feature*. Absent such a showing, the obviousness rejection under §103(a) is without legal merit. Withdrawal of the rejection is respectfully requested.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response to Deposit Account No. 13-3402.

Respectfully submitted,

/Sagun KC/

Sagun KC, Reg. No. L0510
For Applicant(s)

/Anthony J. Zelano/

Anthony J. Zelano, Reg. No. 27,969
Attorney/Agent for Applicant(s)

MILLEN, WHITE, ZELANO
& BRANIGAN, P.C.
Arlington Courthouse Plaza 1, Suite 1400
2200 Clarendon Boulevard
Arlington, Virginia 22201
Telephone: (703) 243-6333
Facsimile: (703) 243-6410

Attorney Docket No.: GMU-0007

Date: April 7, 2011